WHO Update

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COVID-19 response

• WHO EUL scope:
  – Assays for the detection of SARS-CoV-2 nucleic acid;
  – Immunoassays for the detection of SARS-CoV-2 specific antibodies; and
  – RDTs for the detection of SARS-CoV-2 antigens.

• Instructions for manufacturers:
  – NAT and Ag detection IVDs;
  – Ab detection IVDs

https://www.who.int/diagnostics_laboratory/EUL/en/
COVID-19 response cont’d

• Applications status publicly available
• 15 NAT assays listed as of 11 August
• Listings in IMDRF jurisdictions provided
PQDx IVD product dossiers – ToC format

• For WHO PQ applications, product dossiers have been provided in, and reported against, **Summary Technical Documentation (STeD) format**

• In March 2020 WHO PQ Diagnostic Assessments began its transition to the **ToC format** for dossiers and review reports:
  – Dossier requirements, and dossier review documents have been updated to reflect ToC
  – Manufacturers are requested to provide product dossiers in either STeD or ToC format; dossier reviews will be reported using ToC report templates.
  – Training for assessors, and guidance for manufacturers will be provided.

**Implementation, 2021:**
– All product dossiers to be submitted in ToC format.
Inspections and changes

- Shifting from PR to WHOPAR and WHOPIR
- Regulatory flexibility: remote inspection SOP developed
- Update of internal Guideline documents to streamline process in line with MDSAP requirements
- Changes guidance update: Expected to be published for public comments by end of 2020
Updating WHO guidance on post-market and market surveillance of medical devices inc. IVDs

- Expected to be finalised - late 2020
- Encourages feedback from users to manufacturers
- Recommends IMDRF adverse event reporting terminology as foundation for manufacturers to report to NRAs
- Users/manufacturers can report to WHO in absence of adequate regulatory function
- Links to IMDRF UDI, and on-going efforts for WHO medical device nomenclature

New section of WHO website (health topic page for Substandard and Falsified Medical Products) that collates publicly available safety information for medical devices, including IVDs
Pilot CRP for IVDs:
April 2019 – Dec 2019

• Objective
  ✓ Use the WHO-prequalification obtained for m-PIMA HIV-1/2 VL as a basis for country registrations.
  ✓ Assess feasibility of new WHO Collaborative Procedure including impact on registration timelines and requirements for additional country-specific studies.

• Countries
  Pilot was for 5 countries but only 4 countries participated and a 6th country joined later.

• Outcome: 3 registered the product (2 within 90 days and 1 in 179 days.

• Lessons:
  ✓ CRP for diagnostics has proved to be a great innovative mechanism that can accelerate registration of diagnostics and facilitate timely availability of IVDs. Benefits exhibited include; shorter regulatory approval times, reduced workload for NRA experts and reduced need for in-country evaluations based on acceptance of WHO PQ laboratory evaluation and related assessment reports
  ✓ Unclear registration pathways can hinder implementation of CRP.
  ✓ Delays in registration of products can be contributed by inadequate communication amongst key CRP stakeholders.
Public consultation on the draft guideline – 2020

1st First public consultation (15 June to 15 July 2020)

2nd Second public consultation (31 July to 30 September 2020)
Regional Initiatives for medical devices regulation

WHO is supporting:

- The African Medical Devices Forum (AMDF) through the Africa Medicines Regulatory Harmonization Initiative under the African Union to harmonize and strengthen regulation of medical devices in Africa

- Development of guidance documents based on IMDRF recommendations for adoption by the MS.

- Development of training modules for training of NRAs experts.

- Platform for sharing information among NRAs experts.
WHO Global Benchmarking Tool Plus medical devices

• Integration of medical devices into the WHO GBT VI (GBT Plus medical devices)
• Finalization will involve regulatory authorities experts

✓ Discussions started in March 2020 but were postponed due to COVID 19 pandemic
✓ Expected to resume discussions from September 2020 until January 2021
✓ Piloting of the WHO GBT plus medical devices tool in selected countries is planned on Q2 of 2021
Thank you